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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,255	02/14/2001	Bruce Marvin Held	N1205-009	1482
32905	7590	02/12/2004	EXAMINER	
JONDLE & ASSOCIATES P.C. 9085 EAST MINERAL CIRCLE SUITE 200 CENTENNIAL, CO 80112			VOGEL, NANCY S	
		ART UNIT	PAPER NUMBER	
			1636	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/782,255	HELD ET AL.	
	Examiner Nancy Vogel	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 November 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 43-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 43-48 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 06 November 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Claims 43-48 are pending. Receipt of the amendment on 11/6/03 is acknowledged.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/6/03 has been entered.

Drawings

The replacement drawing of Figure 2 was received on Nov. 6, 2003, and is acceptable.

Claim Objections

Claims 43 and 47 are objected to because of the following informalities: The claims have spelling errors. For example, "bases" in claim 43, "prmoter" in claim 47. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification and claims as originally filed do not provide support for the invention as now claimed: "d) identifying subsequences in the sequence of the template promoter which align with the selected segments from the known sequences; e) replacing the identified subsequences in the sequence of the template promoter with the selected segments from the known sequences thereby preparing a first synthetic promoter" of claim 46. There is not sufficient written description for the above-mentioned limitations in the specification as filed. The specification does not contain any guidance or description of identifying subsequences which align with selected segments from known sequences, or for replacing said subsequences in the sequence of the template promoter.

Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to point out sections of the specification which provide sufficient written support for the claims under rejection.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 43-47 rejected under 35 U.S.C. 102(b) as being anticipated by Shibui et al. (Agric. Biol. Chem., 52 (4), 983-988 (1988)).

Shibui et al. disclose a method for preparing a synthetic promoter, the pac promoter, which comprises the steps of (a) comparing the sequence of a template promoter with known nucleic acid sequences; (b) selecting segments [-35 and -10 regions] of said known nucleic acid sequences similar to segments of the template promoter sequence; (c) aligning the selected segments in linear order on the basis of the template promoter to derive a first synthetic promoter; (d) constructing a first synthetic promoter ; and (e) testing the first synthetic promoter for activity (see page 983, first column line 23 - page 984 line 2, and paragraph bridging pages 987 and 988; see Fig. 1). Shibui et al. disclose further modifying the sequence of the first synthetic promoter which does not have improved activity compared to the template promoter to produce a second synthetic promoter and testing said synthetic promoter for activity (see page 988, first column lines 1-23).

Claims 43, 44, 46, 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Vankan et al. (EMBO J., Vol. 8 (12): 3875-3882 (1989) (newly cited).

Vankan et al. disclose a method of preparing a synthetic promoter comprising (a) comparing the sequence of a template promoter with known nucleic acid sequences (the U2 and U5 promoters, lines 1-3, abstract); (b) selecting segments of said known nucleic acid sequences similar to segments of the template promoter sequence (the two elements GTCCACATCG and TATAAATA, abstract lines 6-10); (c) aligning the selected segments in linear order on the basis of the template promoter to derive a first synthetic promoter; (d) constructing a first synthetic promoter (the synthetic promoter, abstract line 9-12) ; and (e) testing the first synthetic promoter for activity (abstract, line 11-13, and page 3876, first col., 3rd complete paragraph through col. 2, end of first complete paragraph). The reference further comprises modifying the sequence of the first synthetic promoter, which does not have improved activity compared to the template promoter (see page 3876, second col., first complete paragraph), including substitutions, and testing it for transcriptional activity (abstract, lines 13-27, and page 3876, col. 2, last paragraph through page 3878).

Claims 43-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Muller (US Pat. No. 6,214,614).

Muller et al. disclose a method for preparing a synthetic promoter comprising the steps of (a) comparing the sequence of a template promoter with known nucleic acid sequences; (b) selecting segments [repressors and cell type-specific regulatory elements and transcription initiation sites] of said known nucleic acid sequences similar to segments of the template promoter sequence; (c) aligning the selected segments in

linear order on the basis of the template promoter to derive a first synthetic promoter; (d) constructing a first synthetic promoter ; and (e) testing the first synthetic promoter for activity. Muller disclose further modifying the sequence of the first synthetic promoter which does not have improved activity compared to the template promoter to produce a second synthetic promoter and testing said synthetic promoter for activity (see col. 4, lines 8 – col. 5 line 10; col. 15, line 60 – col. 17, line 14; Figs . 15 and 16; claims).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ntv



TERRY MCKELVEY
PRIMARY EXAMINER